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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,566	10/16/2000	Dasa Lipovsek	50036/021004	1736

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CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER
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AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 02/07/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/688,566

Applicant(s)

LIPOVSEK ET AL.

Examiner

Maury Audet

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nc address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

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## **DETAILED ACTION**

### **Change of Art Unit Designation**

**Please note:** The Art Unit location of this application in the PTO has changed from Art Unit 1653 to Art Unit 1654. To aid in matching papers in this application, all further correspondence regarding this application should be directed to **Group Art Unit 1654**.

### **Status of the Claims**

Claims 1-43 were originally filed in the present application. An original requirement for restriction was sent on October 2, 2002. Applicant's reply on November 26, 2002 is acknowledged and has been considered. Claims 1-43 remain pending.

### **Supplemental Requirement for Restriction**

If the distinctness and independence of the invention be clear, such requirement will be made before any action upon the merits; however, it may be made at any time before final action in the case at the discretion of the examiner. MPEP 811; 37 CFR 1.142(a). Upon further review of the subject matter contained in the application, a supplemental requirement for invention and species restrictions was warranted.

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**SET I: Non-Antibody Protein, Nucleic Acid, or Process of Making or Using**

1. Claims 1-25, and 32, drawn to a non-antibody protein, classified in class 530, subclass 300+.
2. Claims 26-29, drawn to a non-antibody protein joined to a heterologous protein (i.e. antibody protein), classified in class 530, subclass 300+, class 530, subclass 387.1.
3. Claims 30-31, drawn to a non-antibody protein covalently bound to a nucleic acid, classified in class 530, subclass 300+, class 536, subclass 23.1.
4. Claim 33, drawn to a nucleic acid, classified in class 536, subclass 23.1.
5. Claim 34, drawn to a process of making a derivative non-antibody protein utilizing a scaffold protein, classified in class 530, subclass 333 and/or 344.
6. Claim 35, drawn to a process of making a derivative non-antibody protein utilizing a candidate protein, classified in class 530, subclass 333 and/or 344.
7. Claims 36, drawn to a process of making a compound that binds to a non-antibody (candidate protein), classified in class 530, subclass 333 and/or 344.
8. Claims 37, drawn to a process of using (detecting) a compound in a sample, classified in class 530, subclass 333 and/or 344.

The inventions of SET I are distinct, each from the other because of the following reasons:

The compound of Invention 2 is related to the non-antibody protein of Invention 1 by virtue of also containing the non-antibody protein. However, the compound of Invention 2 and

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the non-antibody protein of Invention I differ in structure (chemically, physically, or pharmacologically) and in function.

The compound of Invention 3 is related to non-antibody protein of Invention 1 by virtue of containing the non-antibody protein. However, the compound of Invention IV and the non-antibody protein of Invention I differ in structure (chemically, physically, or pharmacologically) and in function.

The nucleic acid of Invention 4 is related to the non-antibody protein of Invention 1 by virtue of encoding same. However, the compound of Invention 4 and the non-antibody protein of Invention I differ in structure (chemically, physically, or pharmacologically) and in function.

Invention 1 and Inventions 5-6 are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed is not an obvious process of making the product and the process as claimed can be used to make other and different products; (2) the product as claimed can be made by another and materially different process. (MPEP section 806.05(f)). In the instant case, the product, as claimed, could be made by the materially different process of recombinant production or chemical synthesis.

Invention 8 and Invention 1 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP section 806.05(h)). In the instant case the product as claimed can be used in the materially different process of affinity purification of antibodies.

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**SET II: Non-Antibody Protein, Loop Structure (SEQ ID NOS: 38-140)**

- 9.-111. Claims 38-41, and 43, drawn to a non-antibody protein/loop structure that binds tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), wherein said protein comprises any one of SEQ ID NOS: 38-140, classified in class 530, subclass 300.

Inventions 9-111 of SET II are drawn to non-antibody proteins (and loop structures therein) that differ in structure and in function. Therefore, each protein is patentably distinct one from the other. If any one of Inventions 9-111 is elected, the examination of the claims will be carried out only in-so-far as the claims are drawn to the elected invention.

**SET III: Nucleic Acid**

112. Claim 42, drawn to a nucleic acid encoding a non-antibody protein that binds tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), classified in class 536, subclass 23.1.

The inventions of SET II-III are distinct, each from the other because of the following reasons:

The nucleic acids of Invention 105 are related to the non-antibody proteins/loop structures of Inventions 9-111 by virtue of encoding same. However, the compound of Invention 4 and the non-antibody protein of Invention I differ in structure (chemically, physically, or pharmacologically) and in function.

**Requirement for Species Restriction**

Additionally, a species elections with respect to claim 32 or claims 27-29, will be necessary, should either Invention 1 or Invention 2, respectively, be elected for examination. Specifically, if either invention is elected, one of the following species would necessarily have to be elected:

- I. Claim 32 (Invention 1): one of the 39 species from which the derivative protein is derived; or
- II. Claims 27-29 (Invention 2): one of the six species directed to the heterologous protein.

Should applicant traverse on the ground that the species in claim 32, or claims 27-29, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the sequences unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other sequences or respective inventions.

#### **Summary: Requirement for Restriction**

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Request for Preliminary Set of Amended Claims**

Based on the claims as originally filed, there are many dependencies among the different inventions identified above. As part of the election, Applicant is requested to submit a preliminary set of amended claims, directed to the elected invention, which do not contain any dependencies to any other non-elected inventions (claims), and which are fully descriptive of and include all limitations to that set of claims representing the elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MAA  
February 4, 2003

*Brenda Brumback*  
**BRENDA BRUMBACK**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**